PSI

CUMANN CÓGAISEOIRÍ NA hÉIREANN

The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA

THE PHARMACY REGULATOR

Guidance on Internet Supply of Non-Prescription Medicines

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1. Background

The Common Logo was introduced by the Falsified Medicines Directive to fight against falsified medicines[1]. In order to sell non-prescription medicines[2] over the internet, all websites in the EU must display the Common Logo and be entered in the Internet Supply List of the country from where the website is operated. If selling medicines via the internet in Ireland you must be authorised by the Pharmaceutical Society of Ireland (PSI) to be included in the Internet Supply List and to display the Common Logo.

The Common Logo will help members of the public and other bodies identify the websites that are operating legally and provides a link to the Internet Supply List of all authorised pharmacies and retailers displayed on the PSI website.

2. Application for entry to the Internet Supply List

You must complete the relevant application form to be entered in either Part A or Part B of the Internet Supply List. This entry is only valid for 12 months from the date of entry and a new application must be made every 12 months in order to remain on the Internet Supply List and display the Common Logo. It is an offence to supply medicines via the internet from premises in Ireland if you are not on the Internet Supply List and/or your website does not display the Common Logo.

Part A: only registered retail pharmacies can apply to be on Part A of the list. Pharmacies can legally sell 'pharmacy only' medicines and 'general sale' medicines via the internet.

Part B: premises listed on Part B of the list can only sell 'general sale' medicines via the internet.

Once your details appear on the relevant Internet Supply List, provided the requirements of the legislation[3] are met, non-prescription medicines can be supplied following a request by a member of the public who is located in Ireland, or in another country in the EU. These requirements are outlined below.

Please note the following is NOT permitted from a retail pharmacy business or other premises located in Ireland:

- Supply of prescription only medicines (POMs) via the internet

[1] Falsified medicines are fake medicines that pass themselves off as real, authorised medicines.
[2] Non-prescription medicines, are medicines which can be supplied without the need for a legally valid prescription from an appropriate prescriber.
[3] Falsified Medicines Directive and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 S.I. No. 87 of 2015.

- Supply of a non-prescription medicine via the internet to a purchaser in a country outside the EU

2.1 Website Content

The website selling the non-prescription medicines must contain the following:

- Contact details for the PSI: i.e. Telephone: 01 218 4000, Address: PSI House, Fenian Street, Dublin 2, Email Address: internetsupply@psi.ie
- A link to the PSI website www.psi.ie
- The Common Logo clearly displayed on every page of the website which relates to the sale of medicines online, which links to the Internet Supply List on the PSI website
- A statement stating that a record of each transaction will be retained for 2 years

2.2 Sourcing Medicines

All medicines that you supply must be sourced from an authorised manufacturer or an authorised wholesaler. This is necessary to ensure the quality and safety of the medicines, the security and integrity of the supply chain and reduce the risk of counterfeit medicines entering the supply chain.

A list of all Irish authorised manufacturers and wholesalers is available on the Health Products Regulatory Authority's (HPRA) website (www.hpra.ie).

The authorisation status of a wholesaler or manufacturer based in other EU countries can be checked with the competent authority in the relevant country e.g. the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Where there is difficulty in checking this information with the competent authority in the relevant EEA country, clarification should be sought from the HPRA.

Each medicine should be checked on receipt to ensure that it has an authorisation number, appropriate packaging, a batch number and an appropriate expiry date. The authorisation status of all medicines can be checked on the HPRA website.

If you suspect you have been supplied with a counterfeit, defective or inappropriately authorised medicine, the product should be segregated from legitimate stock, and you should contact the HPRA immediately, or the competent authority of the country from where the medicine was sourced.

Further guidance on the sourcing of medicines can be found in the PSI's *Guidelines on the Sourcing of Medicinal Products for Sale or Supply by a Retail Pharmacy Business*. Whilst this is primarily aimed at the sourcing of medicines by a retail pharmacy business, the principles also apply to non-pharmacy businesses.

2.3 Storing Medicines

Medicines must be stored on the premises specified in the application for entry to the Internet Supply List. This must be fixed premises,[4] which means that it must not be a vehicle or temporary structure, and it must not be a dwelling.
Medicines must be stored in accordance with the requirements of the marketing authorisation of the product. The storage conditions for a medicine are normally specified on the outer packaging of the product or on the patient leaflet contained with the medicine, for example 'Store below 25°C'. Where there are no specified storage conditions, the medicine should be stored at ambient room temperature not exceeding 30°C. Medicines should not be stored in close proximity to sources of heat or cold e.g. unit heaters, artificial lights, in direct sunlight or close to windows. The temperature in the areas when medicines are stored should be monitored to ensure these requirements are met. The area where medicines are stored should be well maintained and kept clean.

The expiry dates of medicines should be checked before supply and a system for stock rotation should be in use to decrease the chance of out of date medicines being supplied to a purchaser.

Further guidance on the storage of medicines can be found in the PSI's *Guidelines on the Storage of Medicinal Products for Sale or Supply by a Retail Pharmacy Business*. Whilst this is primarily aimed at the storage of medicines by a retail pharmacy business, the principles also apply to non-pharmacy businesses.

2.4 Supplying Medicines

Medicines must be supplied from the premises specified in the application for entry to the Internet Supply List and in accordance with the requirements of the marketing authorisation of the product. The packaging used to supply the product must maintain the integrity of the product while in transit to the purchaser. Products which require refrigerated storage must not be supplied unless it can be verified that the storage requirements can be complied with for the entire transit time to the purchaser.

The medicine supplied must hold a marketing authorisation in the EEA country to which you are supplying it e.g. you may only supply a French-authorised medicine pack to a purchaser located in France. It is your responsibility to ensure that you are complying with the laws of the country to which you are supplying medicines.

2.5 Record Keeping

[4] A 'fixed' premises does not include a vehicle, trailer, caravan, or other thing which may be transported on, in, or attached to a vehicle, or, a tent, awning, or hut, shed, or an unroofed or temporary structure or stall or a yard, field roadway, or casual trading area.

The records listed below must be kept at the premises identified in the application for entry on to the Internet Supply List. These records must be maintained in a permanent and unalterable form e.g. PDF or signed hardcopy, and retained for a period of at least **two years** from the date of receipt or supply of the medicine.

1. Every invoice for medicines obtained, which include:
    - the date of the transaction,
    - the name and quantity of the product obtained, and
    - the name and address of the supplier

2. A record of each transaction involving the supply of a medicine to a purchaser, which includes:
    - the order for supply,
    - the date of the transaction,
    - the name and quantity of the product supplied,
    - the name and address of the person to whom the product was supplied

3. A record to show that prior to supplying the product to the purchaser you have checked:

    - the purchaser is over 18 years old,
    - the purchaser is aware that the medicine should be used in accordance with the recommendations for use contained in the product packaging,
    - the total quantity of the product to be supplied in the transaction is a quantity that is reasonably required for the purchasers own treatment, having regard to any previous supply to that purchaser

Some medicines[5] are liable to abuse and/or misuse and you should have a system in place to identify repeated requests for medicines from the same purchaser within a short time frame. Where you suspect a medicine may be being abused or misused a supply should not be made.

In addition to the records to be kept listed above, a pharmacy supplying medicines via the internet must also keep a record to show that prior to supply of the product a registered pharmacist has:

- personally reviewed each order for supply and personally supervises and authorises the supply

- fulfilled the requirement of Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

[5] Examples of non-prescription medicines that are liable to abuse or misuse include laxatives, painkillers and anti-histamines.

Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 requires that in the course of the supply, a registered pharmacist is satisfied that the purchaser is aware of what the appropriate use of the medicine is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.

2.6 Disposing of Medicines

Returned, expired and defective medicines should be segregated from stock. These medicines must not re-enter the supply change and must be disposed of appropriately. Disposal of waste medicines must be in compliance with waste management legislation, primarily the Waste Management Act 1996 (as amended). For further guidance contact Dublin City Council.

Further guidance on the disposal of medicines can be found in the PSI's *Guidelines on the Disposal of Medicinal Products from a Retail Pharmacy Business*. Whilst this is primarily aimed at the disposal of medicines by a retail pharmacy business, the principles also apply to non-pharmacy businesses.

3. Other Legislation

As well as complying with the requirements of the Falsified Medicines Directive and the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015 (S.I. No. 87 of 2015), when selling products to consumers via the internet there is other legislation that your website and business must comply with. It is your responsibility to ensure that you comply with all relevant legislation. For example, you should refer to the Competition and Consumer Protection Commission website (www.ccpc.ie/distance-and-premises-contracts) for further information on the requirements for selling products online. The Competition and Consumer Protection Commission enforces distance selling and e-commerce regulations and can investigate possible breaches of legislation and consumer rights. You should also refer to the Data Protection Commissioner website (www.dataprotection.ie) for further information on your obligations in relation to data protection.

4. Enforcement

It is your responsibility to ensure that the information provided to the PSI on the application for entry to the Internet Supply List is correct and that the PSI is immediately notified of any changes to that information. The PSI may remove a person from the Internet Supply List where they:

- Fail to renew their application every 12 months
- Fail to comply with the requirements of the legislation
- Fail to respond to a written request from the PSI seeking confirmation that they continue to offer to sell non-prescription medicines via the internet
- Have submitted information to the PSI which is false or inaccurate

Please note that all premises selling non-prescription medicines via the internet can be inspected by a PSI or HPRA inspector at any time to ensure the legal requirements are being complied with.

5. Further Information

If you have any questions regarding the supply of medicines via the internet or the process for completing the application form for entry onto the Internet Supply List please email internetsupply@psi.ie.